

IN THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

Claim 1 (currently amended): A pharmaceutical aerosol formulation to be administered by a pressurized metered dose inhalers inhaler, which comprises:
an active ingredient selected from the group consisting of salmeterol, [[or]] a stereoisomer thereof, and a physiologically acceptable salt and solvate thereof, in solution in a propellant system, said propellant system consisting of comprising a liquefied HFA propellant, a co-solvent and 0 to 5% w/w water,
wherein said characterised in that the amount of the cosolvent is present in an amount which is no more than 35% w/w based on the total weight of [[the]] said formulation, and
wherein said formulation has a pH of 2.5 to 5.5, and
wherein said pH of said formulation has been adjusted by addition of a mineral acid.

Claim 2 (currently amended): A pharmaceutical formulation according to claim 1,
wherein the co-solvent is which comprises at least one member selected from the group consisting of a lower alkyl (C1-C4) alcohols alcohol, polyols a polyol, a polyalkylene glycols glycol, a (poly)alkoxy derivatives alcohol, and their combinations mixtures thereof.

Claim 3 (currently amended): A pharmaceutical formulation according to claim 2,
which comprises wherein the cosolvent is ethanol.

Claim 4 (currently amended): A pharmaceutical formulation according to claim 3,
wherein ~~the amount of said water is present in an amount of from 0.5% to 5% w/w and said~~
~~ethanol is present in an amount of no more than 25% w/w.~~

Claim 5 (currently amended): A pharmaceutical formulation according to ~~claims 1-4~~
~~claim 1, wherein the amount of said water is present in an amount up to 3% w/w.~~

Claim 6 (currently amended): A pharmaceutical formulation according to ~~claims 1-5~~
~~claim 1, wherein the a fraction of particles equal to or less than 1.1 µm delivered on actuation~~
~~of [[the]] an inhaler, the superfine fraction which contains said formulation, is higher than or~~
~~equal to 30% as defined by the content of the stages S6-AF of an Andersen Cascade~~
~~Impactor, relative to the content of the stages S6-AF S3-AF of an Andersen Cascade~~
~~Impactor, according to the method referred to in the description on page 16 lines 16 to 24.~~

Claim 7 (currently amended): A pharmaceutical formulation according to ~~claims 1-6~~
~~claim 1, wherein the superfine fraction said fraction of particles equal to or less than 1.1 µm~~
~~delivered on actuation of said inhaler is higher than 40%.~~

Claim 8 (currently amended): A pharmaceutical formulation according to ~~claims 1-7~~
~~claim 1, which comprises wherein the active ingredient is salmeterol xinafoate.~~

Claim 9 (currently amended): A pharmaceutical formulation according to claim 8,
~~wherein the active ingredient is which comprises said salmeterol xinafoate in a concentration~~
~~of between 0.005 and to 0.15% w/v.~~

Claims 10-11 (canceled).

Claim 12 (currently amended): A pharmaceutical formulation according to any preceding claim 1, ~~wherein the propellant includes which comprises~~ one or more hydrofluoroalkanes [HFAs] selected from the group ~~comprising~~ consisting of HFA 134a, [[and]] HFA 227, and mixtures thereof.

Claim 13 (currently amended): A pharmaceutical formulation according to ~~claims 1-12 comprising claim 1, which comprises~~ 0.04% w/v salmeterol, 15% w/w ethanol, and 2% w/w water.

Claim 14 (currently amended): A pharmaceutical formulation according to any preceding claim 1, filled in a canister having part or all of its internal metallic surfaces made of standard aluminium, stainless steel, anodised aluminium or lined with an inert organic coating.

Claim 15 (currently amended): A pharmaceutical formulation according to any preceding claim ~~comprising a further 1, which further comprises at least one~~ active ingredient selected from the ~~class of steroids such as~~ group consisting of beclomethasone dipropionate, fluticasone propionate, ciclesonide, budesonide, the and its 22R-epimer of budesonide, or ~~anticholinergic atropine-like derivatives such as~~ ipratropium bromide, oxitropium bromide, and tiotropium bromide.

Claim 16 (currently amended): A method of preparing [[the]] a pharmaceutical formulation according to formulations of claims 1-15 claim 1, [[the]] said method comprising:

- (a) preparing [[of]] a solution of one or more active ingredients in one or more co-solvents;
- (b) optionally adding a proper amount of water and adjusting the pH of the solution;
- (c) filling ~~of the~~ a device with said solution;
- (d) crimping said device with ~~valves~~ a valve and gassing; and[[.]]
- (e) adding a propellant containing a hydrofluoroalkane (HFA).

Claim 17 (currently amended): A method according to claim 16, wherein [[the]] said device is provided with a valve actuator whose orifice diameter is 0.22 mm.

Claim 18 (currently amended): ~~A pharmaceutical formulation according to any one of claims 1 to 17~~ method for the treatment of a respiratory disease disease, comprising administering an effective amount of a pharmaceutical formulation according to claim 1 to a subject in need thereof.

Claim 19 (currently amended): ~~A pharmaceutical formulation~~ method according to claim 18, wherein said in which the respiratory disease is asthma or Chronic chronic obstructive pulmonary disease (COPD).

Claim 20 (currently amended): ~~A pharmaceutical formulation~~ method according to claim 19, wherein said in which the respiratory disease is due to obstruction of ~~the~~ peripheral airways as a result of inflammation or mucus hypersecretion.

Claim 21 (currently amended): A ~~pharmaceutical formulation~~ method according to claim 18, wherein [[the]] said respiratory disease is pulmonary edema or a surfactant-deficiency related disorder ~~such as acute lung injury (ALI) or acute respiratory distress syndrome (ARDS)~~.

Claim 22 (new): A method according to claim 18, wherein said respiratory disease is acute lung injury or acute respiratory distress syndrome.